I. Disposition of Claims

Claims 1, 6, 30-35, 37, 39, 40, 73, 74, 77, 85, 93, 94, 97, 98, 113-116 are pending. The

Applicants respectively alert the Examiner that Claims 95 and 96 were cancelled in a previous

amendment and do not constitute pending claims as is stated in the Jan. 17, 2007 Office action

(hereinafter referred to as the "Office action"). Further, Claims 114-116 were not listed in the

Office action as pending claims but were previously presented. All claims stand presently

rejected.

**II. General Comments** 

The Applicants express their appreciation for the Examiner's consideration and

acceptance of the Applicants' §112 and §102(b) arguments as well as their §103(a) arguments

with respect to McGinty (USPN 5,288,502, hereinafter referred to as McGinty) in view of

Grinstaff (USPN 5,665,383).

The Applicants respectfully disagree with the Examiner's statement in the Office action

on page 6, third paragraph where it is stated, "Given the broadest reasonable interpretation of the

claim, the particles can still be dissolved in a liquid phase." Upon closer reading of Claim 1 as

well as all the other pending independent claims, the particles referred to "sediment in the

internal liquid phase in contact with the polymer outer membrane." (emphasis added) Since the

act of sedimentation cannot exist if a particle is dissolved in a liquid phase, the Examiner's

referenced conclusion is incorrect.

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### III. Claim Rejections -- 35 U.S.C. §103(a)

All pending claims are assumed to be rejected under 35 U.S.C. §103(a) as being unpatentable over McGinty in view of Gardner (USPN 4532123, hereinafter referred to as Gardner), Busnel et al. (USPN 4930522, hereinafter referred to as Busnel), Scher (USPN 5846554, hereinafter referred to as Scher), and Roth et al. (Rofo. 1979 Sep; 131(3):317-21, hereinafter referred to as Roth). Because Roth is written in German, wherein the abstract that the Examiner provided was translated in English, the Applicants will only reference and analyze Roth in view of the abstract as provided for in M.P.E.P. §706.02.II. The Applicants respectfully traverse the Examiner's §103(a) rejection for the following reasons.

#### III.1 All Claim Limitations Must Be Considered

The references do not teach or suggest all the claim limitations. When evaluating a claim for determining obviousness, all limitations of the claim must be evaluated and all words in a claim must be considered. MPEP §2143.03 states:

"To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art. *re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970)."

Because from the facts derived from the references, as set forth below, the references do not teach or suggest all of the claim limitations based on all of the words in the independent claims, and thus, the rejection is unsupported by the art and should be withdrawn.

### III.1.A. Sedimentation

All of Applicants' independent claims are comprised of the element of sedimentation of a trigger particle in a liquid phase in contact with a polymer membrane. (emphasis added) As stated by the Examiner in the Office action, McGinty does not teach the use of particles. Therefore, McGinty does not teach or suggest (either explicit or implied) sedimentation of a trigger particle in a liquid phase in contact with a polymer membrane. A detailed review of Gardner, Busnel, and Roth revealed no mention of trigger particles and therefore, do not contain a teaching or suggestion (either explicit or implied) of sedimentation of such particles. Scher does mention the use of a solid ultraviolet light protectorant suspended in a liquid. (emphasis added) With respect to the solid ultraviolet light protectorant, Scher's motivation to suspend said material in a liquid is due to his concern that "some biologically active materials are adversely affected by ultraviolet or actinic light; even when they are microencapsulated, the active material in the capsule may still be degraded in the presence of light." (ref: Scher, Column 1, lines 60-63) Scher goes into great detail as to why "suspension" is so important for his invention. (ref: Scher, Column 1, lines 28-32; Column 1, lines 45-59; Column 3, line 66 through Column 4, line 45) Scher also goes as far as stating, "In any event, no matter exactly how it is accomplished, the ultraviolet light protectorant must be thoroughly dispersed in the organic phase." (emphasis added) (ref: Scher, Column 4, lines 43-45) And therefore, Scher suspends and homogeneously disperses his protectorant material to protect his biologically active compounds, which are also homogeneously dispersed in his liquid phase. Further, all of Scher's claims include the limitation of suspension of said protectorant. Because "suspension" and "sedimentation" are two contrasting actions, Scher does not teach or suggest (and arguably teaches away from) sedimentation of particles in a liquid phase in contact with a polymer membrane.

### III.1.B. Melting of a Polymer Membrane

All of Applicants' independent claims are comprised of the temperature of the one or more energy absorbing trigger particle being increased by absorbing energy to melt at least a portion of a polymer outer membrane. As stated supra, McGinty, Gardner, Busnel, and Roth do not mention trigger particles and therefore, do not teach or suggest increasing the temperature of a trigger particle to melt at least a portion of a polymer outer membrane. However, as pointed out by the Examiner, Gardner does teach the utilization of radiation or ultrasonic vibrations to rupture or degrade the wall of a mini-microcapsule, but does not teach or suggest using said radiation or ultrasonic vibrations in combination with a trigger particle. Turning our attention to Scher and as mentioned supra, Scher does teach an ultraviolet light protectorant. However, as argued supra, Scher's protectorant is intended to protect biologically active materials and maintain said biologically active material's characteristics. Stated otherwise, and argued in more detail infra. Scher teaches using a protectorant to protect biologically active material by refracting or dispersing ultraviolet light and thus, arguably teaches away from absorbing energy to melt a polymer membrane. Therefore, when the references are combined, there is no teaching or suggestion (either explicitly or implied) to increase the temperature of a trigger particle to melt at least a portion of a polymer membrane as a single claimed element.

# III.1.C. Energy Absorption Rate of Trigger Particle vs. Absorption Rate of Polymer Membrane

All of Applicants' independent claims are comprised of the element of a trigger particle having a higher specific absorption rate for magnetic, radiofrequency, microwave, or ultrasound energy as opposed to the specific absorption rate of a polymer outer membrane. This element is not taught or suggested, either explicitly or implied, in any of the references. As stated supra, McGinty, Gardner, Busnel, and Roth do not mention trigger particles and therefore, do not teach or suggest a relationship between the absorption rate of a trigger particle when exposed to energy and the absorption rate of a polymer membrane. Scher does teach the use of an ultraviolet light protectorant, but does not teach or suggest a relationship between the absorption rate of his protectorant and the absorption rate of a polymer membrane. Further, Scher's protectorant is designed to protect biologically active material which is sensitive to ultraviolet light or more specifically, to refract ultraviolet light and not to absorb energy. (ref: Scher, Claim 1, which states in part, "...preparing a suspension of the protectant having ... a dispersant which serves to disperse the ultraviolet light protectant in the organic liquid" [emphasis added]) Still further, Scher uses, as his protectorant, (1) titanium dioxide, which has a high refractive index of n=2.4, and/or (2) zinc oxide, which is commonly known in the art to reflect ultraviolet light (ref: Scher, Column 3, lines 46-48). Both titanium dioxide and zinc oxide are commonly used in sunscreen products. Using a material to refract energy as opposed to using a material to absorb energy is in direct contrast with respect to each other. The Examiner mentions in the Office action (ref: page 4, end of second paragraph) that Scher discloses that the use of aluminum powder as a protecting agent is well known in the prior art. (emphasis added) The Applicants respectfully point out that use of particles as a protecting agent is in direct contrast with the use of particles as trigger agents to melt an outer polymer membrane and thereby, release the contents of a microcapsule. Further, although not mentioned in the Office action, Scher mentions that certain ultraviolet absorbers are disclosed in USPN 3,541,203 to Fogle, et al. hereinafter referred to as "Fogle." (ref: Scher, Col. 2, lines 3-8) However, as with Scher, Fogle's motivation is to protect encapsulated insect viruses from the destructed effect of ultraviolet light on these viruses. Fogle is not concerned or motivated to use trigger particles for burst release of encapsulated drugs for therapeutic uses. In fact, Fogle (and Scher) are motivated to release their viruses by grinding pressures (from an insect) or by solution or degradation of an external matrix material. (ref: Fogle, Col. 1, lines 24-27) Logically, it isn't practical to emit an energy source "in the field" thereby releasing encapsulated insect viruses in a pesticide. Aside from the obvious logistical problems of performing such an operation over a wide area, if Fogle or Scher's invention were used in this manner, it would be impossible to determine when to emit the energy source (because once the energy source is emitted, all encapsulated insect viruses are released regardless of whether or not it has been ingested by an insect or not). Stated otherwise, neither **Scher** nor **Fogle** use particles wherein the absorption rate of the particle is selected based on the absorption rate of an outer polymer membrane.

Therefore, the Applicants traverse the Examiner's §103(a) rejection based on M.P.E.P §2143.03 and respectfully argue that a *prima facie* case of obviousness has not been established.

# III.2 There Must Be a Basis in the Art to Combine/Modify

There must be a basis in the art for combining or modifying the references. MPEP §2143.01 provides:

The mere fact that references <u>can</u> be combined or modified does not render the resultant combination obvious unless the prior art also suggest the desirability of the combination.

Accordingly, even if all the elements of a claim are disclosed in various prior art references, the claimed invention taken as a whole cannot be said to be obvious without some logical reason given in the prior art why one of ordinary skill would have been prompted to combine the teachings of the references to arrive at the claimed invention. The Applicants submit the following comments and arguments.

Similar arguments as made *supra* will be made here for completeness purposes. All of Applicants' independent claims are comprised such that the temperature of the one or more energy absorbing trigger particle is increased by absorbing energy to melt at least a portion of a polymer outer membrane. As stated *supra*, **McGinty**, **Gardner**, **Busnel**, and **Roth** do not mention trigger particles and therefore, do not teach or suggest increasing the temperature of a

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trigger particle to melt at least a portion of a polymer outer membrane. However, as pointed out by the Examiner, Gardner does teach the utilization of radiation or ultrasonic vibrations to rupture or degrade the wall of an inner mini-microcapsule. First, Gardner does not teach or suggest using radiation or ultrasonic vibrations to trigger a particle to rupture the wall of an inner mini-microcapsule. In direct contrast, Gardner teaches designing a polymer wall that will rupture when exposed to radiation or ultrasonic vibrations. Second, Gardner specifically teaches away from using radiation or ultrasonic vibrations to rupture an outer polymer membrane. (ref: Gardner, Col. 13, lines 58-63) Gardner states that, "The polymer included in the membrane of the Mini-Microcapsule will be fabricated from a material which can be ruptured or degraded by a treatment process having no corresponding effect upon the outer membrane of the Dual Microcapsule." (emphasis added) Gardner's rationale for his design is described in Gardner, Col. 1, line 59 through Col. 2, line 12. Gardner's motivation is to "mix" two reactive materials together, the first material encapsulated in an inner microcapsule or minimicrocapsule and the second material encapsulated in an outer microcapsule thereby generating a "new entity" that is released to the host via an outer semi-permeable membrane, which is designed to provide a predetermined drug release rate. Simply stated, Gardner does not contain the requisite teaching or suggestion to combine the references for an obviousness rejection that is There is a missing link in the references. commensurate with the Applicants' claims. Specifically, there is no teaching or suggestion in the references for using trigger particles to melt an outer polymer membrane wherein the absorption rate of the trigger particle is higher than the absorption rate of the outer polymer membrane. Without this "missing link," the Examiner's obviousness rejection based on the current references is simply an attempted aggregation of parts (and as discussed above, all the parts of the Applicants' claims do not exist in the references). Absent a "common knowledge" argument, this missing link must be taught or suggested in a reference. It is assumed that the Examiner is not making a "common knowledge" argument because such an argument requires an "instant and unquestionable" standard (ref: M.P.E.P. §2144.03.A). Turning our attention to Scher and as mentioned supra, Scher does teach an ultraviolet light protectorant. However, as argued supra, Scher's protectorant is intended to protect encapsulated biologically active materials to maintain said biologically active material's characteristics by refracting or reflecting ultraviolet light. Scher's protectorant is in direct contrast to the act of absorbing energy. As mentioned supra, Scher, however, does disclose Fogle's invention, which does teach the use of ultraviolet absorption particles. But, Fogle does not teach or suggest using the UV absorption particles as a trigger agent to release the contents of a microcapsule. Further, it was argued supra, that using the UV absorption particles as trigger agents described in Fogle is impractical for Fogle's invention. Further, Applicants' trigger particles aid in the release a microcapsule's internal substances thereby significantly changing the microcapsule's internal character whereby Fogle and Scher's particles are designed to maintain a microcapsule's internal character. Thus, there is no motivation or suggestion, either explicitly or implied, in the present references to combine the teachings of Scher's protectorant or Fogle's UV absorption particles as disclosed in Scher as a basis for using trigger particles to absorb energy and melt an outer polymer membrane.

Therefore, the Applicants traverse the Examiner's rejections based on M.P.E.P. §2143.01 and respectfully argue that a *prima facie* case of obviousness has not been established.

# III.3 Proposed Modification Cannot Change the Principal of Operation of the Primary Reference

The combination or modification of the references in the manner suggested by the Examiner would change the principle of operation of the primary reference (McGinty). M.P.E.P. §2143.01 states:

If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.

Because from the facts derived from the references, as set forth below, the suggested combination or modification would change the principle of operation of the primary reference, the rejection is unsupported by the art and should be withdrawn.

As stated explicitly by the primary reference (McGinty), a principle operation of McGinty's invention is for "long term therapeutic release of a biologically active molecule for therapeutically effective periods of time" (emphasis added) (ref: McGinty, Abstract, lines 18-20). Combining energy absorbing trigger particles designed for "burst" release of a microencapsule's contents, as now claimed in all of Applicants' independent claims, with McGinty would change the principal operation of McGinty's microspheres. As stated supra, a quick release of the Applicants' microcapsule's contents is an inherent characteristic of utilizing

energy absorbing "trigger" particles to melt at least a portion of a polymer outer membrane.

Simply stated, McGinty is not a proper primary reference for the Examiner's proposed

Therefore, the Applicants traverse the Examiner's rejections based on M.P.E.P. §2143.01 and respectfully argue that a *prima facie* case of obviousness has not been established.

## III.4 Teaching Away

obviousness combination.

The references teach away from the Examiner's proposed combination. MPEP §2145 states:

It is improper to combine references where the references teach away from their combination.

Because from the facts derived from the references, as set forth below, the references teach away from their combination, the rejection is unsupported and should be withdrawn.

First, **McGinty** teaches away from the proposed combination because McGinty's invention is designed for "long term therapeutic release of a biologically active molecule for therapeutically effective periods of time" as opposed to a "burst" release.

Second, **Gardner** teaches away from the proposed combination because **Gardner**'s invention is specifically designed such that his <u>outer</u> membrane is <u>not</u> affected by an applied radiation or ultrasonic source.

Third, **Scher** teaches away from the proposed combination because **Scher**'s invention is specifically designed to use reflective or refractive materials in regards to UV light as opposed to

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energy absorbing materials. Scher also teaches away from sedimentation of his particles because Scher teaches a uniform or homogeneous suspension of his particles.

Fourth, Scher discloses Fogle, wherein Fogle teaches away from the proposed combination because Fogle uses UV absorbing particles in a pesticide product designed to be widely distributed over a large area of land such that the UV absorbing particles maintain the effectiveness of the encapsulated insect virus as opposed to rapidly changing the internal structure of a microcapsule. Further, it would be inherently impractical to use Fogle's UV absorbing particles as a trigger particle for Fogle's pesticide purposes (i.e., logistical issues of emitting an artificial energy source over a large area of land and not knowing when to emit an artificial energy source to release the encapsulated insect virus).

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Therefore, the Applicants traverse the Examiner's rejections and respectfully argue that a *prima facie* case of obviousness has not been established.

### IV. Conclusion

The Applicants submit that this paper is fully responsive to the Office action and that all claims stand in a condition for allowance.

The Commissioner is hereby authorized to charge any fee which may be required, or credit any overpayment, to Deposit Account No. 14-0116.

Respectfully submitted,

Date: 4/2/07

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